Stolt Sea Farm California LLC

A subsidiary of Stolt-Nielsen S.A.
9149 East Levee Road, Elverta, CA 95626
Telephone: (916) 991-4420
Facsimile: (916) 991-4334

Documents Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr. rm. 1-23
Rockville, MD 208567

With reference to Docket No. 97N-0217

Dear Sirs

I wish to make the following comments with regards to the development of options to encourage animal drug approvals for minor species and for minor uses. The aquaculture industry (the rearing of plants and animals in water) has many issues with regards to drug use and development of a rational national program to develop and maintain a healthy growing aquaculture industry while maintaining both public health and environmental safety. The FDA has created an INAD and NADA process for the aquaculture industry which still lacks many practical considerations as follows;

The USFWS is actively implementing a national INAD program for their own hatchery system, which deals only with the species and drugs of interest to the Service. The Service does not allow any outsiders, either private individuals or other state agencies from joining their INADS. The Service has been approached many times to allow outsiders to joining their INADS. To date, the Service has resisted. It is in the best interest of FDA to consolidate the data collection process for INADS nationally as much as possible. The natural choice to play a leadership role in this process is the Service, but they actively resist. I would encourage legislation by FDA to mandate that any effort by any government agency to allow for the development and use of drugs on minor animals allow other groups, either private or other government groups to join these efforts, in this case specifically targeting the USFWS to allow others to join their INAD process.

Another major problem facing the aquaculture industry is the large number of species involved. Whereas things like cattle have only one species but many different varieties, the aquaculture industry has many different species. For example trout may have up to 20 different species classified within the grouping of trout, each of which under current law has to be individually investigated and labeled. I would like to see efforts being made to allow groupings of similar animals of different species to facilitate the development of data leading to approval for specific drug uses.

Many countries already have gone through a drug approval process for specific species and drugs. Many of these products enter international trade. If one country has already developed the data that leads to the legal use of a drug on a minor species, consideration must be given to the data developed in the labeling process in other countries, and wherever possible that data used as supporting evidence to allow for the usage of that drug in the same species in the US.

Thank you very much for your consideration.

Sincerely,

Peter Struffenegger

Peter Struffenegger
Manger

97N-0217

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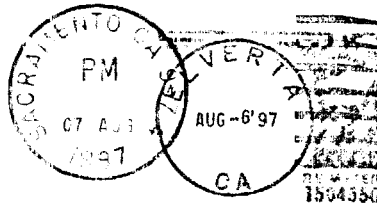
Stolt Sea Farm California LLC
9149 East Levee Road,
Elverta, CA 95626



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FDA
Docket No 97N-0217
12420 Parklawn Dr. rm 1-23
Rockville MD 20857